**UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF VIRGINIA**
**Norfolk Division**

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| PFIZER INC., PFIZER LIMITED and PFIZER IRELAND PHARMACEUTICALS, Plaintiffs and Counterclaim Defendants, v. TEVA PHARMACEUTICALS USA, INC., Defendant and Counterclaim Plaintiff. | Civil Action No. 2:10-cv-00128-RBS-FBS |

**MEMORANDUM IN SUPPORT OF TEVA'S MOTION TO COMPEL PFIZER TO PRODUCE DOCUMENTS RELATING TO SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS**

## I. PRELIMINARY STATEMENT

Defendant and Counterclaim Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") respectfully submits that Plaintiffs and Counterclaim Defendants Pfizer Inc., Pfizer Limited and Pfizer Ireland Pharmaceuticals (collectively, "Pfizer") should be compelled to supplement and complete its production of documents responsive to Teva's Document Request No. 27, which seeks production of data, studies, investigations or analyses of the market or potential market for Viagra®.

Pfizer has limited its production of documents responsive to Teva's Document Request No. 27 to "annual marketing plans, annual operating plans or implementation plans, and annual strategic or tactical plans relating to Viagra®," and has refused to produce any other responsive documents. Pfizer's refusal to produce discovery that is plainly relevant to Pfizer's contentions about alleged commercial success and other secondary indicia of non-obviousness is highly prejudicial to Teva.

Pfizer was supposed to complete its production of documents responsive to Teva's outstanding discovery requests by February 4, 2011. Expert reports directed to secondary considerations of non-obviousness are due in a few short weeks. To avoid the prejudice that Teva will suffer if Pfizer is permitted to refuse to produce discovery that Teva and its experts need to test, challenge and meet Pfizer's contentions with respect to secondary indicia of non-obviousness, Teva respectfully asks the Court to enter an Order that rejects Pfizer's attempt to limit its production of marketing documents to "annual plans" and compels Pfizer to produce all of the data, studies, investigations or analyses of the market or potential market for Viagra® in Pfizer's possession, custody or control.

Pfizer's refusal to produce other responsive marketing documents that are relevant to its contentions about commercial success are especially prejudicial to Teva under the circumstances in this case. The patent-in-suit is a method patent that claims methods of administering a compound called sildenafil to a patient. The claims of the patent-in-suit do not cover the compound itself. For the reasons explained below, Pfizer cannot rely on the alleged commercial success of its sildenafil tablets (Viagra®) unless Pfizer proves that there is a nexus between the alleged commercial success of its sildenafil product and the particular methods of administration described in the asserted claims of the patent-in-suit. If the alleged commercial success of Viagra® is due to some other factor, such as the invention of the sildenafil compound itself that is claimed in another patent that is not at issue in this action, Pfizer cannot rely on the alleged commercial success of Viagra® as secondary proof that the asserted method claims of the patent-in-suit are not obvious.

Teva has a right to rebut any attempt by Pfizer to establish that the success of Viagra® is due to the methods of administering sildenafil claimed in the patent-in-suit, and to do so by demonstrating that other factors, such as the sildenafil compound that is the active ingredient in Viagra®, or the extraordinary marketing efforts and expenditures that Pfizer has devoted to Viagra®, are responsible for any alleged commercial success of Pfizer's product. To test and challenge the contentions and arguments that Pfizer will advance with respect to secondary indicia of non-obviousness, however, Teva's experts need to review and analyze not only the sanitized summary annual marketing plans that Pfizer is willing to produce, but also the raw data and marketing documents that were generated contemporaneously with the events and developments that transpired throughout the life of Pfizer's product.

Pfizer does not deny that documents requested by Teva relating to data, studies, investigations or analyses of the market or potential market for Viagra® are relevant to the issues framed by the pleadings and raised by the parties respective contentions. Pfizer simply refuses to produce anything other than the annual plans that its experts no doubt will rely upon, hoping that its refusal to produce the underlying documents and other relevant marketing documents will compromise Teva's experts' ability to meet and refute Pfizer's contentions.

## II. PFIZER SHOULD BE COMPELLED TO PRODUCE DOCUMENTS THAT RELATE TO THE MARKET OR POTENTIAL MARKET FOR VIAGRA®

Teva's Document Request No. 27 seeks production of:

> All documents that constitute, refer or relate to data, studies, investigations or analyses of the market or potential market for Viagra® for the treatments described in Pfizer's prescribing information ("indications and usage" section) for Viagra® including, without limitation, data, studies, investigations or analyses of third parties.

Ex. 1, Teva's First Set of Document Requests, at 22.

Although Teva's request plainly is not limited to annual summaries or plans, Pfizer has agreed to produce only "annual marketing plans, annual operating plans or implementation plans, and annual strategic or tactical plans relating to Viagra®," and has refused to search for or produce any of the other documents in its possession, custody or control that are responsive to Document Request No. 27. *See* Ex. 2, August 30, 2010 Letter from Aaron Stiefel to Keith A. Zullow at 2; Ex. 9, August 13, 2010 Letter from Aaron Stiefel to Keith A. Zullow at 1.[1] In an attempt to resolve the dispute between the parties with respect to marketing documents, Teva

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[1] Pfizer initially responded to Teva's Document Request No. 27 by asserting that it would only produce "responsive, non-privileged documents which preceded the commercial launch of Viagra®." Ex. 4, Pfizer's Amended Responses to Teva's First Set of Document Requests at 28. Pfizer later changed its position and agreed to produce documents after the commercial launch of Viagra®, but agreed only to produce annual marketing plans. Ex. 9, August 13, 2010 Letter from Aaron Stiefel to Keith A. Zullow at 1.

proposed a compromise and suggested that Pfizer produce weekly, monthly, quarterly and annual marketing plans and reports relating to Viagra®. Ex. 3, October 5, 2010 Letter from Joshua A. Whitehill to Aaron Stiefel at 1. Pfizer rejected Teva's proposal and refused to produce marketing documents other than annual plans. Ex. 5, November 1, 2010 Letter from Aaron Stiefel to Joshua A. Whitehill. In recent discussions between counsel for the parties, Pfizer has indicated that there are no "regular" weekly or monthly reports, and has failed to agree to search for additional responsive documents other than annual plans. Teva's Document Request No. 27, of course, is not limited to annual marketing plans. Pfizer's refusal to search for additional responsive documents is unreasonable, unjustifiable and prejudicial.

Pfizer cannot deny that documents that constitute, refer or relate to data, studies, investigations or analyses of the market or potential market for Viagra® are relevant to Pfizer's contention that Viagra® is commercially successful and that the success of that product should be regarded as secondary evidence that the asserted claims of the patent-in-suit are not obvious. Evidence of the alleged commercial success of a product, however, is not relevant to the obviousness of the inventions described in the asserted claims of the patent-in-suit unless the patentee demonstrates that there is a nexus between the patented invention and the claimed success, *i.e.* that the sales of the product are due to the properties of the invention claimed in the patent. *Ormco Corp. v. Align Tech., Inc*., 463 F.3d 1299, 1311–12 (Fed. Cir. 2006) ("Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success."); *see also Iron Grip Barbell Co. v. USA Sports, Inc*., 392 F.3d 1317, 1324 (Fed. Cir. 2004) (explaining that a "nexus must be established between the merits of the claimed invention and evidence of commercial success before that evidence may become relevant to the issue of obviousness") (internal quotations

omitted). Evidence that commercial success is due to other factors that are not related to the attributes of the invention, such as the marketing or cost of the commercial product, shows that the required nexus does not exist. *Oscar Mayer Foods Corp. v. ConAgra, Inc*., 94-cv-1247, 1994 WL 712488, at *4 (Fed. Cir. Dec. 22, 1994) (holding that "commercial success is probative only if it reflects a demand for that inventor's solution to the problem, not a response to marketing efforts or an effect of some other cause"). Evidence of sales by itself does not establish a nexus between commercial success and the claimed invention. *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp*., 264 F.3d 1344, 1355 (Fed. Cir. 2001).

Although the question whether alleged commercial success should be regarded as evidence of non-obviousness ultimately is decided by an objective analysis, admissions by the parties about the cause of the alleged success are relevant to that determination. In *McNeil-PPC, Inc. v. Perrigo Co*., 516 F. Supp. 2d 238 (S.D.N.Y. 2007), the Court relied on plaintiffs' own marketing study before the launch of Pepcid Complete, which concluded that the product was not perceived to fulfill an unmet need, and held that plaintiffs failed to make a showing sufficient to prove that the commercial success of the product was attributable to the inventions claimed in the patent-in-suit. *Id*. at 254-55 & n.8. The Federal Circuit relied on similar information in *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.* to support its decision that the challenger admitted commercial success. *Demaco Corp.*, 851 F.2d 1387, 1394 (Fed. Cir. 1988).

The most salient evidence relevant to the question whether the alleged commercial success of Viagra® should be regarded as secondary evidence of the non-obviousness of the asserted claims of the patent-in-suit is not likely to be contained in the sanitized summary annual marketing plans that Pfizer has agreed to produce. Instead, the documents that are most likely to reflect, evidence and explain Pfizer's reaction to competitive threats, the changing emphasis of

its marketing efforts and whether any alleged commercial success is due to the patented method at issue in this action or some other patent or factors, are the contemporaneous marketing and sales data and information that Pfizer prepared, collected and used at the time those issues arose. Contemporaneous marketing documents, for example, are far more likely than the summary information provided in annual marketing plans to contain admissions about the cause of the alleged commercial success of Viagra®, and whether any alleged commercial success was a consequence of the method of administering sildenafil claimed in the patent-in-suit, or was due to "irrelevant commercial or economic factors." *Oscar Mayer Foods Corp.,* 1994 WL 712488, at *4 (holding that "commercial success is probative only if it reflects a demand for that inventor's solution to the problem, not a response to marketing efforts or an effect of some other cause"). Pfizer's responses to Teva's contention interrogatories make it plain that Pfizer believes that sales and marketing information for specific points in time – rather than annual plan information -- may be relevant to the issue of the invalidity of the patent-in-suit. *See* Ex. 6, Pfizer's Supplemental Responses to Teva's First Set of Interrogatories, Response to Interrogatory No. 3 at 19 ("Pfizer sales of Viagra® in April 1998 were over $248 million.") Teva needs specific and precise information about the marketing of Viagra® to rebut Pfizer's claims regarding commercial success. Pfizer's refusal to produce anything other than annual marketing plans is improper and prejudicial.

Pfizer based its refusal to search for and produce marketing and forecasting plans (other than annual marketing plans) on the ground that the documents requested by Teva are not relevant. Ex. 7, July 30, 2010 Letter from Aaron Stiefel to Keith A. Zullow at 1 (Pfizer does "not see the relevance of documents concerning the market for Viagra® through the twelve years since launch."). Pfizer's argument is wrong and it should be rejected. Pfizer intends to rely upon

the alleged commercial success of Viagra® as a secondary factor to prove that the asserted claims of the patent-in-suit are not obvious. *See* Ex. 6, Pfizer's Supplemental Responses to Teva's First Set of Interrogatories, Response to Teva Interrogatory No. 3 at 18-20. For the reasons explained above, the documents requested by Teva relate directly to the issue of commercial success, and the nexus or lack of nexus between that alleged commercial success and the method of administering sildenafil described in the asserted claims of the patent-in-suit. Teva needs those documents to test and challenge Pfizer's contention that there is a nexus between Pfizer's sales of Viagra® and the method of administration claimed in the patent-in-suit.

The documents sought by Teva's Document Request No. 27 are highly relevant to the claims and defenses of the parties. Pfizer's argument that Document Request No. 27 is unduly burdensome should be rejected. Pfizer asserts that Document Request No. 27 requires Pfizer to search all of its files and produce every document that relates to the marketing of Viagra® over the past 13 years. *See* Ex. 8, February 9, 2011 E-mail from Aaron Stiefel to Michael DeVincenzo at 1. Document Request No. 27, however, is not that broad – it does not seek production of all documents in Pfizer's possession, custody or control that relate in any way to the marketing of Viagra®. Document Request No. 27 only seeks documents that constitute, refer or relate to data, studies, investigations or analyses of the market or potential market for Viagra®. Teva respectfully submits that Pfizer should be ordered to conduct a reasonably diligent search for and to produce the documents requested by Document Request No. 27. Pfizer should not be permitted to limit its production of documents to the annual marketing plans that it no doubt intends to rely upon to attempt to prove its contentions regarding commercial success. As the party objecting on grounds of "undue burden," Pfizer must show not only undue burden or expense, but also that the "burden or expense is unreasonable in light of the benefits to be

secured from the discovery." *Hammond v. Lowe's Home Centers, Inc.*, 216 F.R.D. 666, 674 (D. Kan. 2003).

During a telephone conference on February 9, 2011 in which the parties conferred about their dispute with respect to Document Request No. 27, counsel for Teva requested that Pfizer conduct a reasonable search for responsive documents. Less than an hour after that telephone conference, Pfizer's counsel stated that his understanding "is that there are no regular weekly, monthly or quarterly marketing reports regarding Viagra." Ex. 8, February 9, 2011 E-mail from Aaron Stiefel to Michael DeVincenzo.[2] Pfizer's report that there are no "regular" weekly, monthly or quarterly marketing reports regarding Viagra® and suggestion that the only responsive documents in Pfizer's possession are annual marketing plans strains credulity. Pfizer should be compelled to produce documents that constitute, refer or relate to data, studies, investigations or analyses of the market or potential market for Viagra® without regard to whether those documents can be characterized as "reports" or whether they were produced on a "regular" basis.

## III. CONCLUSION

Unless Pfizer is prepared to forego relying on the alleged commercial success of Viagra® and other secondary indicia of non-obviousness for all purposes in this action, Pfizer should not be permitted to limit its production to annual marketing plans, and should be compelled to search for, collect and produce other documents responsive to Teva's Document Request No. 27.

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[2] Pfizer's counsel also stated that Teva should question Mr. Maffezoli about the types of marketing reports that Pfizer prepared for Viagra®. *Id.* Teva believes that the requested marketing documents should be produced before the Rule 30(b)(6) deposition directed to marketing, so that the deposition can be conducted efficiently and will not need to be continued after Pfizer produces the relevant documents.

Dated: February 10, 2011

By: /s/

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 10th day of February, 2011, I will electronically file the foregoing Memorandum in Support of Teva's Motion to Compel Pfizer to Produce Documents Relating to Secondary Considerations of Non-Obviousness with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing to the following counsel of record:

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